

REMARKS

With the entry of this Response, Claims 1-3, 10-12, and 25-26 are currently under consideration. Claims 17-24 and 30-32 have been withdrawn as directed to non-elected subject matter. In this Response, Applicant has amended Claims 1, 11-12, and 21-22.

Claim 1 has been amended to recite that the composition comprises “a skin explant”. Claim 1 has further been amended to recite that the composition also comprises “a glucosaminoglycan-enriched media”. Support for the amendments to Claim 1 can be found throughout the as-filed Specification and as-filed claims and at least at page 2 (paragraphs 8-13), page 9 (paragraph 54), and pages 33-34 (paragraphs 120-121).

Claims 11-12 have been amended to recite that the “composition” rather than the “skin” is preserved at a temperature above freezing or at a temperature below freezing. Support for the amendments to Claims 11-12 can be found throughout the as-filed Specification and as-filed claims and at least at page 4 (paragraph 23) and page 20 (paragraph 94). Applicant has also amended withdrawn Claims 21-22 to recite that the “composition” rather than the “skin” is preserved above or below a freezing temperature. The support for the amendments to Claims 21-22 can be found throughout the as-filed Specification and as-filed claims and at least at page 4 (paragraph 23) and page 20 (paragraph 94).

Applicant submits that the amendments to the Listing of Claims do not constitute new subject matter and do not raise new issues. In view of the arguments presented below, Applicant respectfully requests the allowance of all pending claims.

TRAVERSAL OF WITHDRAWN CLAIMS

Applicant respectfully traverses the Office Action’s withdrawal from consideration of Claims 30-32. 37 C.F.R. § 1.475 provides that national stage applications shall relate to one invention or to a group of inventions so linked as to form *a single general inventive concept*. The requirement of a single inventive concept is fulfilled when there is a technical relationship within the claimed subject matter involving one or more of the same or corresponding special technical features. The special technical feature must define a contribution that the claimed subject matter makes over the prior art.

While 37 C.F.R. § 1.475 discusses the determination of unity of invention. In particular, 37 C.F.R. § 1.475(b) states that “claims to different categories of invention will be considered to

have unity of invention if the claims are drawn only to one of the following combinations”, the converse statement is not true. (emphasis added). For instance, 37 C.F.R. § 1.475(b) does not say that claims not falling within the listed categories requires or establishes a lack unity of invention. 37 C.F.R. § 1.475(c) emphasizes this point, stating that “if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.” (emphasis added). Again, the rule does not state that unity of invention would not exist, but rather that there was no guarantee it did exist. As noted above, the correct standard for determining unity of invention is stated in rule 37 C.F.R. § 1.475(a).

According to M.P.E.P. § 1850, “unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims.” (emphasis added). M.P.E.P. § 1850 states that “[i]f the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention.”

The Restriction Requirement issued on May 24, 2010 stated that the technical feature linking Groups I-III is a cell with hyaluronan in the absence of serum. The Restriction Requirement stated that this “feature is well known in the art according to Guienne et al. (1999)” (herein Guienne). In the Response to the Restriction Requirement, Applicant elected Group I (Claims 1-16 and 25-29), which group the Office Action described as being “drawn to a composition comprising a cell and hyaluronan in the absence of serum.” In the Response filed January 7, 2011, Applicant added Claims 30-32, which are also drawn to the composition of Claim 1, which comprises a skin explant and a glucosaminoglycan-enriched media in the absence of serum. The present Office Action has now withdrawn Guienne as the basis of the rejection under 35 U.S.C. § 102. In doing so, Applicant respectfully submits that the Office Action acknowledged that Guienne does not teach or disclose the technical feature for which it was previously relied upon. As the claims under consideration (Claims 1-3, 10-12, and 25-26) and Claims 30-32 all share the same technical feature, which defines a contribution over the prior art, Applicant submits that the Office Action’s withdrawal of Claims 30-32 is inappropriate.

To this end, Applicant notes that neither Guienne nor the references cited in the present Office Action teach or disclose a composition comprising a skin explant and a

glucosaminoglycan-enriched media in the absence of serum. Because each of Claims 1-3, 10-12, 25-26, and now 30-32 comprise the special technical feature that defines a contribution over the prior art, these claims possess unity of invention. For this reason alone, Applicant submits that the Office Action's withdrawal of Claims 30-32 is improper. Accordingly, Applicant respectfully requests rejoinder and examination of at least Claims 30-32. Furthermore, in view of the failure of the cited references to teach or disclose the defining technical feature, Applicant respectfully requests rejoinder and examination of Claims 17-24, each of which comprises the composition of Claim 1.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Office Action rejected Claims 11-12 under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant respectfully traverses this rejection to the extent that the rejection applies to the claims as amended. In this Response, Applicant has amended Claims 11-12, and Applicant submits that the amendments to Claims 11-12 render this rejection moot. Therefore, Applicant respectfully requests that the Examiner withdraw this rejection and allow these claims.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

A. CLAIMS 1, 3, 10-12, 25 AND 26

The Office Action rejected Claims 1, 3, 10-12, 25, and 26 under 35 U.S.C. § 102(b) as anticipated by Boyce *et al.* (1993) *Plast. Reconstruct. Surg.* (herein "Boyce"). The Office Action stated "Boyce et al. teach the composite grafts of cultured skin cells (epidermal keratinocytes and dermal fibroblasts; skin grafts; thus considered as a sheet) and glycosaminoglycan . . ." (Office Action, p. 3). Applicant respectfully traverses this rejection to the extent that the rejection applies to the claims as amended.

Under 35 U.S.C. § 102(b), a proper rejection of a claim requires that a single prior art reference disclose each and every element of the claim. Alternatively, anticipation requires that each and every element of the claimed invention be embodied in a single prior art device or practice. For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (*See, e.g., W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983)). Thus, in making a rejection under 35 U.S.C. § 102, the Patent Office is burdened with establishing that

the cited art teaches each and every limitation of the claims. Applicant respectfully submits that the present Office Action does not meet this burden in view of the claims as currently amended.

Currently amended independent Claim 1 recites “A composition comprising a skin explant and a glucosaminoglycan-enriched media in the absence of serum.” Applicant notes that as Claims 3, 10-12, and 25-26 depend from Claim 1, each of these dependent claims incorporates all of the elements of currently pending Claim 1.

Boyce teaches the enzymatic and mechanical disaggregation of biopsies and the culturing of epidermal keratinocytes and dermal fibroblasts. (p. 633, col. 1, par. 3). In other words, Boyce disassembles a biopsy into several component parts. Using an artificial construct, Boyce then recombines some of those component parts into what the Office Action described as a “composite graft”. Boyce describes this “composite graft” as a “cultured cell-biopolymer skin analogue”.

These are not teachings of the intact skin of a skin explant as claimed in Applicant’s currently pending claims. In fact, Boyce fails entirely to provide any teaching or disclosure of a skin explant, much less a composition comprising a skin explant and a glucosaminoglycan-enriched media in the absence of serum. For at least these reasons, Applicant respectfully submits that Boyce does not teach or disclose each and every element of Applicant’s currently pending independent Claim 1. Consequently, Boyce fails to anticipate Claim 1 and dependent Claims 3, 10-12, and 25-26. Applicant respectfully requests that the Examiner withdraw this rejection and allow Claims 1, 3, 10-12, and 25-26.

B. CLAIMS 1-3, 10-12, 25, AND 26

The Office Action rejected Claims 1-3, 10-12, and 25-26 under 35 U.S.C. § 102(b) as anticipated by Cram *et al.* (1983) J. Trauma (herein “Cram”) in view of Fraser *et al.* (1997) J. Intern. Med. (herein “Fraser”). The Office Action stated that “Cram *et al.* teach human skin stored at 4 °C in RPMI tissue culture medium in the absence of serum” and that Fraser teaches that “human skin inherently contains hyaluronic acid or hyaluronan.” (Office Action, p. 4). Applicant respectfully traverses this rejection to the extent that the rejection applies to the claims as amended.

The proper standard for a rejection under 35 U.S.C. § 102 is set forth above. Applicant respectfully submits that the present Office Action does not meet this burden in view of the claims as currently amended.

Currently amended independent Claim 1 recites “A composition comprising a skin explant and a glucosaminoglycan-enriched media in the absence of serum.” Applicant notes that as Claims 2-3, 10-12, and 25-26 depend from Claim 1, each of these dependent claims incorporates all of the elements of currently pending Claim 1.

Cram evaluates human skin stored in five different. As described by Applicant in Applicant's Specification, Fraser offers a general description of the biology of hyaluronan in various tissues and organs, and provides a table summarizing the distribution of hyaluronan in the skin, muscles, intestines, and other organs for the rat.

In making this rejection, the Office Action stated that the media of Cram coupled with the skin of Fraser (and the hyaluronan within that skin) is a teaching of the claimed composition. However, Cram and Fraser are not teachings of Applicant's currently pending claims, which recite a composition comprising a skin explant and a glucosaminoglycan-enriched media. As neither Cram nor Fraser teaches a media that comprises a glucosaminoglycan, neither Cram nor Fraser teaches a glucosaminoglycan-enriched media. Furthermore, the addition of skin to a media, as suggested by the Office Action, is not a teaching of the claimed composition. The claimed composition does not comprise a glucosaminoglycan-enriched media simply because a skin explant (and the hyaluronan within that skin) has been added to the composition. Rather, Applicants' claimed composition comprises both a skin explant and a glucosaminoglycan-enriched media. As the skin explant and the glucosaminoglycan-enriched media are separate components of the claimed composition, Cram and Fraser fail to teach the claimed composition.

For at least these reasons, Applicant respectfully submits that Cram and Fraser do not teach or disclose each and every element of Applicant's currently pending independent Claim 1. Consequently, Cram and Fraser fail to anticipate Claim 1 and dependent Claims 2-3, 10-12, and 25-26. Applicants respectfully request that the Examiner withdraw this rejection and allow Claims 1-3, 10-12, and 25-26.

CONCLUSION

The foregoing is a complete response to the Final Office Action mailed February 14, 2011. Applicant respectfully submits that all of the claims under consideration are patentable. Early and favorable consideration is solicited. Applicant files this Response solely to facilitate prosecution. As such, Applicant reserves the right to pursue claims of broader or similar scope as originally filed in a continuation application or other application after allowance of the present application.

If the Examiner believes there are other issues that can be resolved by a telephone interview, or that there are informalities that remain in the application that may be corrected by the Examiner's amendment, a telephone call to the undersigned attorney at (678) 420-9408 is respectfully solicited.

Applicants respectfully submit that no fee is due; however, Applicant authorizes the Commissioner to charge to Deposit Account No. 14-0629 any additional fee that may be required.

Respectfully submitted,

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